DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

Office for Human Research Protections
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April 15, 2004

George F. Kalf, Ph.D., CIP
Professor of Biochemistry/Molecular Pharmacology
Associate Dean for Scientific Affairs
Director, Division of Human Subjects Protection
Office of Scientific Affairs
Thomas Jefferson University
1015 Chestnut Street, Suite 1100
Philadelphia, PA 19107

**RE: Human Research Subject Protections Under Federalwide Assurance (FWA) 2109**

Dear Dr. Kalf:

The Office for Human Research Protections (OHRP) has reviewed your letters dated February 23 and March 25, 2004 regarding allegations of noncompliance with Department of Health and Human Services (HHS) regulations for the protection of human research subjects (45 CFR Part 46). OHRP has determined that the corrective actions summarized below appropriately address the issues raised:

> HHS regulations at 45 CFR 46.111(a) state that, in order to approve research covered by the regulations, the IRB shall determine that, when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. OHRP finds that research records were stored in an unlocked file cabinet in a common area copy room during the day for a two-week period, where individuals not associated with the research may have had easy access to these files, which contained private, identifiable information, and might even have been able to photocopy them.
>
> **Corrective Action**: OHRP acknowledges that the research records are now being stored in a locked office and the research coordinator has been counseled that research files must reside in a locked file cabinet and in a locked room when she is not present.

As a result, there should be no need for further involvement of OHRP in this matter. Of course, OHRP must be notified should new information be identified which might alter this determination.

OHRP appreciates the continued commitment of your institution to the protection of human research subjects. Please do not hesitate to contact me should you have any questions.

Sincerely,

Kristina C. Borror, Ph.D.
Director
Division of Compliance Oversight

cc:

Dr. David G. Brock, Chairperson, IRB #1, TJU
Dr. Stephen P. Weinstein, Chairperson, IRB #2, TJU
Dr. Gregory Mokrynski, Chairperson, IRB #3, TJU
Dr. David Lepay, Director, Good Clinical Practices Program, FDA
Dr. Bernard Schwetz, OHRP
Dr. Melody H. Lin, OHRP
Dr. Michael Carome, OHRP
Ms. Shirley Hicks, OHRP
Ms Janice Walden, OHRP
Ms. Melinda Hill, OHRP
Ms. Patricia El-Hinnawy, OHRP